



U.S. Agency for International Development, Washington, DC 20523-1427

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**Issuance Date:** May 7, 2001  
**Closing Date:** July 2, 2001  
**Closing Time:** 2:00 P.M. EST

**Subject:** Request for Applications (RFA) Number M/OP-01-686  
HEALTH TECH IV

The United States Agency for International Development (USAID) is seeking applications for a five year Cooperative Agreement from an organization/consortium for funding a program for HEALTH TECH IV. The authority for the RFA is found in the Foreign Assistance Act of 1961, as amended, and the Federal Grant and Cooperative Agreement Act of 1977.

The Recipient will be responsible for ensuring achievement of the G/PHN Center's five Strategic Support objectives through the development and/or introduction of new low-cost health, nutrition, and family planning technologies and the provision of supporting

technical assistance. Please refer to the Program Description for a complete statement of the HEALTH TECH IV goals and expected results.

Pursuant to 22 CFR 226.81, it is USAID policy not to award profit under assistance instruments. However, all reasonable, allocable, and allowable expenses, both direct and indirect, which are related to the grant program and are in accordance with applicable cost standards (22 CFR 226, OMB Circular A-122 for non-profit organization, OMB Circular A-21 for universities, and the Federal Acquisition Regulation (FAR) Part 31 for-profit organizations), may be paid under the grant.

Subject to the availability of funds, USAID intends to provide approximately \$17.0 million in total USAID funding to be allocated over the five year period. It is anticipated that USAID Missions will contribute nearly \$5 million of this \$17 million. In addition, the awardee will be required to cost-share an additional minimum 10%, for a total minimum USAID/Recipient program cost of \$18.7 million. USAID reserves the right to fund any or none of the applications submitted.

For the purposes of this program, this RFA is being issued and consists of this cover letter and the following:

1. Section A - Grant Application Format;
2. Section B - Evaluation Criteria;
3. Section C – HEALTH TECH IV Program Description;
4. Section D - Certifications, Assurances, and Other Statements of Applicant/Grantee;
5. Section E - Annexes

For the purposes of this RFA, the term "Grant" is synonymous with "Cooperative Agreement"; "Grantee" is synonymous with "Recipient"; and "Grant Officer" is synonymous with "Agreement Officer".

If you decide to submit an application, it should be received by 2:00 p.m. Eastern Standard Time, on the date indicated at the top of this cover letter at the place designated below for receipt of applications. Applications and modifications thereof shall be submitted in envelopes with the name and address of the applicant and RFA # M/OP-01-686 inscribed thereon, to:

(By U.S. Mail)

U.S. Agency for International Development  
Office of Procurement, M/OP/G/PHN  
1300 Pennsylvania Avenue, Room 7.09-130  
Attn: Mr. Emmanuel E. Atsalinos, Grant Officer  
Washington, DC 20523-7100

(By All Other Means of Delivery)

U.S. Agency for International Development  
Office of Procurement  
M/OP/G/PHN, Attn: Mr. Emmanuel E. Atsalinos, Grant Officer  
1300 Pennsylvania Avenue, Room 7.09-130  
Washington, DC 20523-7100

Applicants are requested to submit both technical and cost portions of their applications in separate volumes. Award will be made to that responsible applicant(s) whose application(s) offers the greatest program value to the Government, considering technical merit, cost and other factors.

Issuance of this RFA does not constitute an award commitment on the part of the Government, nor does it commit the Government to pay for costs incurred in the preparation and submission of an application. Further, the Government reserves the right to reject any or all applications received. In addition, final award of any resultant grant(s) cannot be made until funds have been fully appropriated, allocated, and committed through internal USAID procedures. While it is anticipated that these procedures will be successfully completed, potential applicants are hereby notified of these requirements and conditions for award. Applications are submitted at the risk of the applicant; should circumstances prevent award of a cooperative agreement, all preparation and submission costs are at the applicant's expense.

The preferred method of distribution of USAID procurement information is via the Internet. This RFA and any future amendments can be downloaded from the Agency Web Site. The World Wide Web Address is <http://www.usaid.gov>. Select Business and Procurement from the home page, then "USAID Procurements". On the following screen, select "Download Available USAID Solicitations". Receipt of this RFA through INTERNET must be confirmed by written notification to the contact person noted below. It is the responsibility of the recipient of the application document to ensure that it has been received from INTERNET in its entirety and USAID bears no responsibility for data errors resulting from transmission or conversion processes.

In the event of an inconsistency between the documents comprising this RFA, it shall be resolved by the following descending order of precedence:

- (a) Section B - Evaluation Criteria;
- (b) Section A - Grant Application Format;
- (c) Section C - the Program Description;
- (d) This Cover Letter.

Any questions concerning this RFA should be submitted in writing to Ms. Georgia Fuller, via facsimile at (202) 216-3132. Please notify Ms. Fuller of transmittal of your questions

via telephone at (202) 712-0551. Questions also may be submitted by e-mail to [gfuller@usaid.gov](mailto:gfuller@usaid.gov).

If there are problems in downloading the RFA off the INTERNET, please contact the USAID INTERNET Coordinator on (202) 712-4442. Applicants should retain for their records one copy of all enclosures which accompany their application.

Sincerely,

Emmanuel E. Atsalinos  
Grant Officer  
M/OP/G/PHN  
Office of Procurement

## **SECTION A GRANT APPLICATION FORMAT**

### **Preparation Guidelines**

All applications received by the deadline will be reviewed for responsiveness to the specifications outlined in these guidelines and the application format. Section B addresses the technical evaluation procedures for the applications. Applications that are submitted late or are incomplete run the risk of not being considered in the review process.

Applications shall be submitted in two separate parts: (a) technical and (b) cost or business application. Technical portions of applications should be submitted in an original and six (6) copies and cost portions of applications in an original and two (2) copies.

The application should be prepared according to the structural format set forth below. Applications must be submitted no later than the date and time indicated on the cover page of this RFA, to the location indicated on page 3 of the cover letter accompanying this RFA.

Technical applications should be specific, complete and presented concisely. The applications should demonstrate the applicant's capabilities and expertise with respect to achieving the goals of this HEALTH TECH IV RFA. The applications should take into account the technical evaluation criteria found in Section B.

Applicants should retain for their records one copy of the application and all enclosures which accompany their application. Erasures or other changes must be initialed by the person signing the application. To facilitate the competitive review of the applications, USAID will consider only applications conforming to the format prescribed below.

### **Technical Application Format**

USAID requests that Applications be kept as concise as possible. Detailed information should be presented only when required by Specific RFA instructions. Applications are limited to 100 pages (excluding annexes) and must be printed on 8-1/2 inch by 11 inch paper (210 mm by 297 mm paper), single spaced, 10 pitch type or larger). USAID requests that applications provide all information required by following the general format described below:

1. Technical Approach
2. Key Personnel and Staffing
3. Organizational and Management Capability
4. Past Performance and Corporate Capability

### **Cost Application Format**

The Cost or Business Application is to be submitted under separate cover from the technical application. Certain documents are required to be submitted by an applicant in order for an Grant Officer to make a determination of responsibility. However, it is USAID policy not to burden applicants with undue reporting requirements if that information is readily available through other sources.

The following sections describe the documentation that applicants for Cooperative Agreements must submit to USAID prior to award. While there is no page limit for this portion, applicants are encouraged to be as concise as possible, but still provide the necessary detail to address the following:

- A. A copy of the program description that was detailed in the applicants program description, formatted in Word97; **and** a copy of the budget in Excel format, on a 3-1/2" diskette.
- B. Include a budget with an accompanying budget narrative which provides in detail the total costs for implementation of the program your organization is proposing. The budget should be submitted using Standard Form 424 and 424A which can be downloaded from the USAID web site;
  - the breakdown of all costs associated with the program according to costs of, if applicable, headquarters, regional and/or country offices;
  - the breakdown of all costs according to each partner organization involved in the program;
  - the costs associated with external, expatriate technical assistance and those associated with local in-country technical assistance;
  - the breakdown of the financial and in-kind contributions of all organizations involved in implementing this Cooperative Agreement;
  - potential contributions of non-USAID or private commercial donors to this Cooperative Agreement;
  - your procurement plan for commodities (note that contraceptives and other health commodities will not be provided under this Cooperative Agreement).

- C. A current Negotiated Indirect Cost Rate Agreement;
- D. Required certifications and representations (as attached):
- E. Cost share has been recommended to be 10% of the total estimated amount. If the applicant proposes a cost share of less than 10%, it will be deemed as not responsive, and will be removed from further consideration.
- F. Applicants shall also submit the following information:
  - 1. Copies of the applicant's financial reports for the previous 3-year period, which have been audited by a certified public accountant or other auditor satisfactory to USAID;
  - 2. Projected budget, cash flow and organizational chart;
  - 3. A copy of the organization's accounting manual.
- G. In accordance with ADS 303.5.9a(2)(a-e), applicants should submit any additional evidence of responsibility deemed necessary for the Grant Officer to make a determination of responsibility. The information submitted should substantiate that the Applicant:
  - 1. Has adequate financial resources or the ability to obtain such resources as required during the performance of the award.
  - 2. Has the ability to comply with the award conditions, taking into account all existing and currently prospective commitments of the applicant, nongovernmental and governmental.
  - 3. Has a satisfactory record of performance. Past relevant unsatisfactory performance is ordinarily sufficient to justify a finding of non-responsibility, unless there is clear evidence of subsequent satisfactory performance.
  - 4. Has a satisfactory record of integrity and business; and
  - 5. Is otherwise qualified and eligible to receive a grant under applicable laws and regulations (e.g., EEO).
- H. In accordance with ADS 303.5.9a(3)(a-e), applicants that have never received a grant, cooperative agreement or contract from the U.S. Government are required to submit a copy of their accounting manual. If a copy has already been submitted to the U.S. Government, the applicant should advise which Federal Office has a copy.

In addition to the aforementioned guidelines, the applicant is requested to take note of the following:

- I. Unnecessarily Elaborate Applications - Unnecessarily elaborate brochures or other presentations beyond those sufficient to present a complete and effective application in response to this RFA are not desired and may be construed as an indication of the applicant's lack of cost consciousness. Elaborate art work, expensive paper and bindings, and expensive visual and other presentation aids are neither necessary nor wanted.
- J. Acknowledgement of Amendments to the RFA - Applicants shall acknowledge receipt of any amendment to this RFA by signing and returning the amendment. The Government must receive the acknowledgement by the time specified for receipt of applications.
- K. Receipt of Applications - Applications must be received at the place designated and by the date and time specified in the cover letter of this RFA.
- L. Submission of Applications:
  - 1. Applications and modifications thereof shall be submitted in sealed envelopes or packages (1) addressed to the office specified in the Cover Letter of this RFA, and (2) showing the time specified for receipt, the RFA number, and the name and address of the applicant.
  - 2. Telegraphic applications will not be considered; however, applications may be modified by written or telegraphic notice, if that notice is received by the time specified for receipt of applications.
- M. Preparation of Applications:
  - 1. Applicants are expected to review, understand, and comply with all aspects of this RFA. Failure to do so will be at the applicant's risk.
  - 2. Each applicant shall furnish the information required by this RFA. The applicant shall sign the application and print or type its name on the Cover Page of the technical and cost applications. Erasures or other changes must be initialed by the person signing the application. Applications signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.
  - 3. Applicants who include data that they do not want disclosed to the public for any purpose or used by the U.S. Government except for evaluation purposes, should:



(a) Mark the title page with the following legend:

"This application includes data that shall not be disclosed outside the U.S. Government and shall not be duplicated, used, or disclosed - in whole or in part - for any purpose other than to evaluate this application. If, however, a grant is awarded to this applicant as a result of - or in connection with - the submission of this data, the U.S. Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting grant. This restriction does not limit the U.S. Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]"; and

(b) Mark each sheet of data it wishes to restrict with the following legend:

"Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this application."

N. Explanation to Prospective Applicants - Any prospective applicant desiring an explanation or interpretation of this RFA must request it in writing within three weeks of receipt of the application to allow a reply to reach all prospective applicants before the submission of their applications. Oral explanations or instructions given before award of a Grant will not be binding. Any information given to a prospective applicant concerning this RFA will be furnished promptly to all other prospective applicants as an amendment of this RFA, if that information is necessary in submitting applications or if the lack of it would be prejudicial to any other prospective applicants.

O. Grant Award:

1. The Government may award one or more Grants resulting from this RFA to the responsible applicant(s) whose application(s) conforming to this RFA offers the greatest value (see also Section B of this RFA). The Government may (a) reject any or all applications, (b) accept other than the lowest cost application, (c) accept more than one application (see Section B, Evaluation Criteria), (d) accept alternate applications, and (e) waive informalities and minor irregularities in applications received.
2. The Government may award one or more Grant(s) on the basis of initial applications received, without discussions. Therefore, each initial application should contain the applicant's best terms from a cost and technical standpoint.

3. A written award mailed or otherwise furnished to the successful applicant(s) within the time for acceptance specified either in the application(s) or in this RFA (whichever is later) shall result in a binding Grant without further action by either party. Before the application's specified expiration time, the Government may accept an application, whether or not there are negotiations after its receipt, unless a written notice of withdrawal is received before award. Negotiations conducted after receipt of an application do not constitute a rejection or counteroffer by the Government.
  4. Neither financial data submitted with an application nor representations concerning facilities or financing, will form a part of the resulting Grant(s).
- P. Authority to Obligate the Government - The Grant Officer is the only individual who may legally commit the Government to the expenditure of public funds. No costs chargeable to the proposed Grant may be incurred before receipt of either a fully executed Grant or a specific, written authorization from the Grant Officer.

END OF SECTION A

## **SECTION B**

### **EVALUATION CRITERIA**

The criteria presented below have been tailored to the requirements of this particular RFA. Applicants should note that these criteria serve to: (a) identify the significant matters which applicants should address in their applications and (b) set the standard against which all applications will be evaluated. To facilitate the review of applications, applicants should organize the narrative sections of their applications in the same order as the evaluation criteria.

Technical applications will be evaluated by a Technical Committee of USAID representatives, and others as deemed appropriate, in accordance with the technical evaluation criteria set forth below. Concurrently, the cost portion of the application of all applicants will be reviewed and costs will be evaluated for general reasonableness, allowability, and allocability. Applicants are also invited to explain in their applications how they propose to meet the minimum cost-sharing requirement of 10 percent. To the extent that they are necessary, negotiations may be conducted with the applicant(s) whose applications(s) has (have) a reasonable chance of being selected for award.

Subject to the availability of funds, USAID expects to award one cooperative agreement. This award will be made to the responsible applicant whose application offers the greatest program value to the Government, considering technical merit, cost, and other factors. Applications will be ranked in accordance with the technical evaluation criteria below. USAID reserves the right to determine the resulting level of funding for the cooperative agreement.

The analysis of the cost application will consist of a review of the cost portion of an applicant's application to determine if the overall costs proposed are reasonable and realistic for the work to be performed, if the costs reflect the applicant's understanding of the requirements, and if the costs are consistent with the technical application.

To be considered for funding, applications must meet the following minimum technical qualification. Applications must originate with an eligible United States-based organization. The authorized source and origin of goods and nationality of suppliers of goods and services is the United States (Geographic Code 000).

Organizations which are not U.S.-based may participate as partners with, and at the behest of, the U.S. organizations, but may not be direct grantees. Waivers of the authorized Nationality from Geographic Code 000 to Code 935 will be entertained on a case-by-case basis.

Local source procurement will be authorized to the extent permitted in USAID regulations in accordance with ADS 311.

## TECHNICAL EVALUATION CRITERIA

### INSTRUCTIONS FOR THE PREPARATION OF THE TECHNICAL PROPOSAL

- (a) The Technical Proposal in response to this solicitation should address how the applicant intends to achieve the objectives of the HEALTH TECH IV Program Description. It should demonstrate a clear understanding of the key issues, challenges and opportunities in the field of technology product development and technology product introduction. The Proposal should describe the approach the applicant intends to follow in order to identify, prioritize and address these issues.

The Technical Proposal should describe how the applicant intends to access the full scope of expertise required achieve the objectives of the Health Tech IV program. It should demonstrate a clear understanding of the work to be undertaken and the responsibilities of all parties involved.

In the case where a consortium of organizations is formed to attain the full scope of expertise, the lead organization, or primary applicant, must be clearly identified as well as the relationship among members of the consortium.

- (b) The technical proposal should be organized by the technical evaluation criteria.
- (c) The past performance references required by this section should be included as an annex or attachment.
- (d) The technical proposal shall be limited to a **maximum of 100 pages of text**, excluding any attachments and annexes that contain resumes on proposed personnel and references on past performance. The technical proposal should, at a minimum, include the following:

#### 1. Technical Approach

*Overall understanding.* The applicant should describe:

- Challenges associated with the achievement of the goals of health, nutrition and family planning programs that may be addressed by the development and/or introduction of technologies;
- Challenges associated with both the development and the introduction of health, nutrition and family planning technologies, as they may relate to both the public and private sector;
- Current strategies and approaches used to develop, introduce and promote the appropriate use and public health impact of health, nutrition and family planning technologies, as they may

relate to both the public and private sector; and what the applicant feels are the strengths and weaknesses of these current strategies and approaches.

- Current strategies, challenges and opportunities for developing and organizing comprehensive multipartner organizational consortia to carry out the range, depth and mix of expertise required to identify and address critical challenges and opportunities in technology product development and introduction.

The applicant should draw from its own experience or other knowledge with respect to the challenges and issues identified above, and provide specific examples of how these challenges or issues have been addressed (successfully or not) in specific programs and activities.

**Technical approach issues:** This section should present the specific strategies by which the applicant will address the major issues associated with health, nutrition and family planning technology development and introduction, and how the applicant will achieve the Health Tech IV cooperative agreement objectives.

In addition, as a means to illustrating these strategies and approaches, the applicant should develop one each of the following for submission with the proposal:

- A. a sample **product development plan**
  - B. a sample **product introduction plan**
  - C. a sample **feasibility analysis**
- A. and B. The sample **product development plan** and the sample **product introduction plan** should describe the strategic and technical approaches that the applicant would follow for the development/introduction of a technology that is of major relevance to one of four following priority areas: child survival, immunization, diagnostics, family planning. Each submission should address a different priority area; i.e., no priority area should be used more than once in the submissions. Each proposal should identify critical issues, challenges and opportunities, and outline the specific strategies and approaches the applicant would proposed to follow. The Product Development Plan and the Product Introduction Plan should include information such as is described in the Health Tech IV Program Description (see under Section "Technical Activities"). The applicant should propose and provide a rationale for how the applicant would assess the public health impact of **technology product introduction** outcomes achieved under the Health Tech IV program.
- C. The Health Tech IV Program focuses on addressing impediments to the effective delivery of health, nutrition and family planning technical assistance and services in developing countries through the appropriate use of low-cost, durable, and easy-to-use technologies. During the course of the cooperative agreement, USAID will be requesting that the recipient provide feasibility analyses in order to aid USAID staff in assessing whether or not an issue merits further attention and should be given priority, and whether feasible solutions exist to address an identified technology development and technology introduction need.

The applicant is requested to complete the following exercise as a means to providing insight into the applicant's strategic approach and capabilities and, thereby, to aid in the technical evaluation of this proposal.

A sample feasibility analysis should be developed in response to the following scenario. The particular scenario has been chosen primarily because it represents a scenario not addressed under previous Health Tech agreements.

***Please clearly note that, although in this RFA proposal the applicant is being asked to address a topic that is of relevance to the human immunodeficiency virus (HIV)/AIDS epidemic, the Health Tech IV program will initially have a very limited focus on HIV/AIDS issues.***

**Scenario:** Globally, an estimated 36 million people are currently living with HIV infection. Ninety-five percent of the 36 million HIV-infected individuals in the world live in resource-poor countries. In this scenario, assume that it were possible to provide universal access to medical treatment (with an unlimited supply of quality drugs and HIV immunodiagnostics, such as the currently used HIV test kits, and of trained personnel) by those living with HIV in resource-poor countries. What would be the needs/challenges related to ensuring the provision of safe and efficacious therapeutic strategies in resource-poor settings that could be addressed by the development of new or improved technologies? What is the process by which the applicant would identify and prioritize these needs? What new or improved technologies might be developed to address these needs/challenges and are they feasible? What needs/challenges would the applicant recommend as high priority for targeting Health Tech IV efforts?

In this exercise, the applicant should:

- 1) review and analyze the major challenges and opportunities;
- 2) prioritize the set of challenges and propose which are the most amenable to be addressed and resulting in a public health impact;
- 3) propose and discuss short-term and long-term strategies and propose feasible potential technology development and/or introduction solutions for addressing one or two priority challenges; and
- 4) develop a feasibility analysis for one of them.

D. As a means for providing the applicant with an opportunity to demonstrate or discuss its interest, knowledge and/or innovative thinking, the applicant is requested to submit a description of and rationale for 2-4 potential “priority” areas to target for health, nutrition or family planning technology development and/or technology introduction that have not been identified as priority areas in the Health Tech IV Program Description (as listed in the section “Priority Areas...” in the Program Description. The proposed areas should be **consistent with USAID strategic objectives** (as described in section A, under "Objective", in the Program Description).

## 2. Key Personnel and Staffing:

**Key Personnel.** As noted in the Health Tech IV Program description, USAID requires applicants to propose a Project Leader. The applicant may propose additional key personnel, if desired, but no more than five (5) total.

This section should describe the key personnel position(s) proposed, the responsibilities and authority of the/each position, and the rationale for the position(s) in relation to the achievement of the cooperative agreement objectives and execution of the principal areas of work described in the program description.

Additionally, this section should:

- (a) Discuss the capabilities and experience of the proposed candidate(s) for the key personnel position(s);
- (b) Demonstrate that the proposed key personnel has/have proven leadership skills in approaches, international policy and international programming in technology development and technology introduction;
- (c) Provide evidence that the proposed key personnel candidate(s) has/have a proven technical and management track record in the successful execution of programs and achievement of objectives similar to those described in the Health Tech IV program description. (Specific critical skill and capability areas that the key personnel should possess are provided in the Health Tech IV program description.)
- (d) Provide evidence that the proposed key personnel have been able to recruit and retain highly qualified technical staff.
- (e) Provide letters of commitment from key personnel.

**Staffing.** This portion of the proposal should include a detailed description of the applicant's proposed staffing and recruiting plan for the cooperative agreement as a whole. This section should include the following items:

- (a) Proposed staffing plan to provide “**core** capabilities” (refer to Program Description, Section B, under "Core Capabilities"): The proposed staffing plan should provide the titles and numbers of the positions, as well as job descriptions and responsibilities for the proposed positions.
- (b) Plan should include the names of individuals proposed for each position, if known, and the institutional affiliation of each if not a direct hire employee.
- (c) Proposed staffing and/or recruiting plan to provide “**related** capabilities” (refer to Program Description, Section B, under "Related Capabilities"): as above.
- (d) Staffing plan rationale: The applicant should provide a clear rationale for why the proposed team staffing plan will ensure the execution of the principal areas of work described in the Program description.
- (e) Resumes for all individuals proposed for key and staff positions should be included as an annex.



### 3. Organizational and Management Capability

**Organizational Structure.** The applicant should provide a detailed description and rationale of the organizational structure that will support the implementation of this cooperative agreement. The description should include a table or diagram describing the organizational structure, functions and responsibilities in relation to effective implementation, as well as the rationale for the proposed organization structure. The description must include proposed lines of responsibility, authority, and communication, including those with country programs and technical support tasks.

**Management Plan.** The applicant should provide a detailed management plan that clearly defines:

- (a) How the cooperative agreement will be managed to assure the greatest possible achievement of the activity's strategic objective and results; policies and procedures for managing and directing the program in order to maximize productivity and quality, and to ensure the early identification and resolution of problems;
- (b) How the proposed project team will interface with both the applicant's corporate structure and USAID activity management structure; and
- (c) If the applicant includes a partnership, consortium, or subcontracts/sub-agreements with one or more than one organization, the management plan must provide details of this arrangement. These details must specify: (i) the roles of each organization; (ii) the types of mechanism linking the organizations; and (iii) the organizational structures and management procedures that will be used to avoid any delays, added cost, or restriction on provision of the most appropriate staffing or expertise

### 4. Past Performance and Corporate Capability

This section requires the applicant to provide information on the relevance of the applicant's previous experience (in the past three years) to the program description in the Health Tech IV Program Description, and experience in implementing similar technical leadership as well as similar technical assistance in the various countries and geographic regions where USAID works.

This section should also provide information about experience in developing comprehensive plans for, participating in, and/or providing leadership to multi-partner collaborations or initiatives involving multinational donor agencies or foundations and their partners on issues relevant to those described in the Program Description.

This section should include all aspects of performance, including overall quality and impact of the technology product and/or associated technology product introduction activities and/or technical assistance or services. In addition, information about the financial and administrative aspects of performance should be provided.

Evidence of the applicant's responsiveness to clients' needs and client satisfaction should also be presented. In a separate annex, the applicant should provide a listing of all agreements the applicant has held to perform work (in the past three years) similar to that described for Health Tech IV in the program description, and should include recent email, fax, telephone numbers and addresses for references.

## 5. Cost Consciousness.

In order to accomplish the greatest possible results and make the greatest possible contribution to improved health systems, the recipient must ensure that the greatest possible proportion of resources invested in the cooperative agreement be spent on technical functions. There should be minimum expenditure (consistent with effective implementation) on administration, management, and ancillary functions.

In this section the applicant should specify approaches and procedures that will be used to minimize headquarters, administrative, and other non-operational costs, and to assure that the greatest amount of resources are utilized in achieving results and impact. This should include identification of specific procedures to minimize "allocable" costs (costs of maintaining the headquarters and management staff, structure, and functions of the activity), direct costs for other headquarters and ancillary staff and functions, as well as direct and indirect costs for operations and activities.

## **Technical Evaluation Criteria**

The matrix below provides a breakdown of the relative weight and point distribution for the technical evaluation criteria that will be used to evaluate proposals received. Unless otherwise indicated, all sub-elements under a technical evaluation factor shall be weighted equally. The following section describes the primary technical criteria that will be applied in scoring each factor.

Scoring matrix

		Unit score	Sub-unit Score
1.0	Technical Approach	35	
1.1	Overall understanding		5
1.2	Technical approach issues		30
2.0	Key personnel & staffing	15	
2.1	Key personnel		10
2.2	General staffing		5
3.0	Organization & Management	10	

4.0	Past Performance	30	
5.0.	Cost Consciousness	10	
	Total possible	100	

1. Technical Understanding and Approach (35 points)

**Overall understanding (5 pts).** Evaluation of this section will be based on:

- a. The extent to which the applicant demonstrates an understanding of the challenges and issues associated with current approaches to technology product development and technology product introduction, as they may relate to both the public and private sector.
- b. The extent to which the applicant demonstrates an understanding of the role of key stakeholders and of the issues of appropriate use and public health impact as they relate to technology introduction.

**Technical approach issues (30 pts):** Evaluation of this section will be based on the review of the submitted materials, including those requested in the "Instructions for the Preparation of the Technical Proposal" under "Technical Approach Issues", which together should illustrate the applicant's understanding of, and proposed strategies to address, the major issues associated with progress in these areas.

2. Qualifications and Experience of Key Personnel and Staff (15 points)

**Key Personnel (10 pts).** Evaluation of this section will be based upon:

- a. The extent to which the proposed key personnel have demonstrated success in guiding and executing programs similar to that described in the program description;
- b. The degree to which the proposed key personnel and staff meet or exceed the required qualifications to provide the critical capabilities identified in the program description;
- c. The degree to which the proposed key personnel and staff have demonstrated ability and a record of developing and introducing health, nutrition and family planning technologies and of providing technical assistance related to the development and introduction of health, nutrition and family planning technology in developing countries;
- d. The degree to which the proposed key personnel have demonstrated proven leadership skills in technology development and introduction;

- e. The degree to which key personnel have demonstrated success in developing and implementing comprehensive multipartner plans, forming organizational alliances, and organizing partners to effectively execute plans;
- f. The extent to which the proposed key personnel have demonstrated the ability to recruit and retain highly qualified technical staff.

**General Staffing (5 pts).** Evaluation of this section will be based upon:

- a. The likelihood that the proposed staffing plan will provide the needed technical expertise and programmatic support in a timely and cost-effective manner, thus helping to ensure successful implementation of the program description in Program description.
- b. The likelihood that the proposed recruiting and hiring program will help ensure the availability of technical expertise throughout the life of the cooperative agreement.

### 3. Organizational and Management Capability (10 points)

Organizational and management capacity will be based on the applicant's demonstrated:

- a. Administrative and managerial capability to plan, implement and evaluate project activities, including those with multiple collaborators/partners, including multilaterals, such as WHO and UNICEF, as well as with other public and private sector partners such as CDC, industry, academia, NGOs, foundations and others.

Management effectiveness of the proposed structure and relations among elements of the structure. Structures that do not have a clear focus on technical results will be judged inadequate.

- b. Ability to assess the need for and to strategically and effectively utilize, when appropriate, expertise found outside the applicant's personnel and staff that increases or complements expertise provided by the applicant.

Anticipated effectiveness of the management approaches and procedures proposed, and the ability of these approaches to support the achievement of the results and objectives of the cooperative agreement. Evaluation will consider the degree to which the proposed plan will ensure the availability and use of implementation and resource information for management, help to identify and resolve problems, and facilitate internal coordination and communication.

The extent to which the plan demonstrates sound business practices in response to the requirements in the program description.

#### 4. Past Performance (30 points)

Evaluation of past performance will be based on the extent to which the applicant demonstrates satisfactory technical, financial and managerial performance in conducting other programs similar to the cooperative agreement in the past three years. The applicant's past performance will be evaluated based upon its ability to independently demonstrate through references provided by former or current clients and/or partners with respect to the following:

- a. Demonstrated technical leadership and experience in the achievement of the program description objectives;
- b. Adherence to the terms and conditions of its contracts, grants, or cooperative agreements;
- c. Demonstrated responsiveness and commitment to partner or client satisfaction;
- d. Pursuing excellence in all aspects of its business;
- e. Successful financial performance.

Each sub-element above (a-e) will count as 6 points of the total score for each past performance reference. If there are multiple past performance reports, an average will be developed for the element. For example, past performance is worth 30 points. If a applicant's proposal provides one past performance reference, and scores the maximum 6 points on each sub-element, then 30 points would be awarded. If an applicant has 3 past performance reports and scored 30, 25, and 20 on each report, then those points would be added together (75) and divided by 3 reports, for a total award of 25 points.

#### 5. Cost Consciousness (10%)

Evaluation of this section will be based on the specificity and potential impact of the applicants' proposed approaches and procedures for minimizing headquarters, administrative, non-operational, allocable and direct costs. Additionally, evaluation will be based on the degree to which the applicants' approaches and procedures will likely ensure that available resources are used to the maximum extent possible for technical functions and activities that will lead to achievement of results and impact.

END OF SECTION B

## SECTION C

# HEALTH TECH IV PROGRAM DESCRIPTION

## A. OBJECTIVE

The Health Tech IV project will undertake activities to support the achievement of United States Agency for International Development (USAID) Agency Goal 4 and the achievement of the strategic objectives of the USAID Global Bureau's Center for Population, Health and Nutrition (G/PHN Center); USAID Regional and other Central Bureaus; and USAID missions. The major emphasis of Health Tech IV will be on the achievement of the five Strategic Support Objectives (SOs) of the USAID Global Bureau's Center for Population, Health and Nutrition (G/PHN Center). The principal objective of the Health Tech IV project will be to support these objectives through the development and/or introduction of new low-cost health, nutrition, and family planning technologies and the provision of supporting technical assistance. In order to maximize the public health impact of these technologies, a major focus of the Health Tech IV project will be on activities that support the introduction and appropriate use of these technologies into health, nutrition and family planning programs in developing countries.

USAID Agency Goal 4 is the stabilization of world population and the protection of human health. The G/PHN Center's Strategic Support Objectives include:

- Increased use by women and men of voluntary practices that contribute to reduced fertility
- Increased use of key maternal health and nutrition interventions
- Increased use of key child health and nutrition interventions
- Increased use of improved, effective and sustainable responses to reduce HIV transmission and mitigate the impact of the HIV/AIDS pandemic
- Increased use of effective interventions to reduce the threat of infectious diseases of major public health importance.

For further information refer to USAID websites listed in Annex E.

The continuum from product conception to full product deployment is complex and requires a broad range of skills and inputs. The Health Tech IV project will have key personnel and staff that will be able to direct activities for all parts of the continuum, including those activities necessary for achieving the successful introduction and appropriate use of these technologies. Activities in the continuum could range from engineering and product design, to support to develop international and national policies, to resolving procurement and logistical infrastructure issues, and to providing context- and local-specific training.

Project activities will be guided by product development plans (PDPs) or product introduction plans (PIPs) that will attempt to chart all of the activities required to take a product /concept from its current state to full deployment and appropriate use. These plans may involve the input from and activities undertaken by a number of collaborating partners. These plans will help to ensure that the public health impact that results from the use of new/improved technologies is maximized and is achieved as cost-effectively and rapidly as possible.

## **B. INTRODUCTION**

### **Roles of the public and private sectors**

Impediments to the effective delivery of health, nutrition and family planning technical assistance and services in developing countries can frequently be addressed through the appropriate use of low-cost, durable, and easy-to-use technologies. Such technologies can, for example: assist in the safe delivery of vaccines, contraceptives and medicines; assist in the diagnosis of infectious diseases and detection of nutrition deficiencies and low birth weight; promote cost reduction by improving efficiency; and foster the provision of more equitable access to and distribution of limited health care and family planning technical assistance. Frequently, these technologies can address impediments to the achievement of USAID PHN Center, other USAID Central and Regional Bureau and USAID Mission strategic objectives.

Historically, the private sector has been reluctant to make the substantial investments required to develop health, nutrition and family planning technologies targeted for use primarily in the developing world due to the high risk and limited potential return on investments. The vast majority of investments required to develop, evaluate and produce these technologies have been made by the public sector.

Public sector investments have been based on the premise that once the necessary steps leading to (and including) the successful commercialization of a product (e.g., successful field trials, the acquisition of the requisite international endorsements, the identification of a commercial partner, etc.) were achieved, the entrepreneurial forces of the private sector would automatically take over and subsequently ensure the wide use and improved public health impact of these products. Unfortunately, this has not been the case with most public health products targeted for use in the developing world. Many products of well-intentioned public sector investments have unnecessarily languished for want of carefully developed strategies and approaches to ensure their introduction and appropriate use.

However, there are some success stories. In most of the cases in which public sector products have been successfully deployed, there has been significant additional public and private sector investment in a number of critical areas to ensure their deployment and integration into relevant programs. For example, in response to the growing concerns over the safety of injection practices, in the late 1980s and early 1990s USAID made investments in the development of single use syringes. These investments resulted in the development of two devices that were

ultimately licensed to Becton Dickinson for further development and manufacture. For several years one product, SoloShot, an auto-disable (AD) syringe, was available through the UNICEF catalog for procurement for use in developing countries. Unfortunately, it was rarely purchased. Over the course of the next four to six years USAID made significant investments and worked with all of the concerned partners to increase the global awareness of the magnitude of the disease burden resulting from the provision of unsafe injections. This effort has resulted in a growing appreciation of the potential public health impact resulting from the use of AD syringes. As a result, over 350 million AD syringes will be procured by UNICEF this year for use in immunization programs. Moreover, these purchases have demonstrated to the private sector that there are legitimate markets for AD syringes specifically designed for use in developing countries. There now more than 10 manufacturers of AD syringes throughout the world with additional manufacturers coming on board each year.

## **Role of USAID**

Since 1987, USAID has been supporting the development of health, nutrition and family planning technologies and the provision of technical assistance through Health Tech agreements with the Program for Appropriate Technology in Health (PATH). The Health Tech project was initiated and designed to address the great need for low-cost and easy-to-use technologies by health, nutrition and family planning programs in developing countries.

In 1995, a USAID G/PHN/HN working group reviewed the available information regarding the role of technologies in implementing the USAID Population, Health and Nutrition strategy and in achieving sustainable self-sufficiency in health care and family planning programs. The group found that aside from USAID, few other organizations supported the development of low-cost health and family planning technologies and related technical assistance to developing countries. In addition, respondents to a 1995 survey of bilateral and multilateral organizations conducted by the Office of Health and Nutrition acknowledged the unique and important role played by USAID and the groups that they support.

The 1995 working group also observed that the commercial sector historically has been reluctant to invest in research and development (R&D) for developing country markets due to limited profit potential, except through collaborations with the public sector. A 1999 World Bank analysis of private sector investments in the development of vaccines targeted at diseases that predominately effect populations in the developing world indicates that, at least for vaccines, the situation has not changed in recent years. Companies are reluctant to make the substantial investments required to develop, evaluate and produce products for the perceived limited markets in the developing world. A similar situation can be demonstrated for the development of simple, inexpensive, rapid diagnostics for diseases common in these regions.

## **Role of Health Tech IV**

The Health Tech IV project will provide a mechanism for the assessment, development, adaptation, testing, transfer, introduction/application, appropriate use, and where appropriate, local manufacturing of health, nutrition and family planning technologies that are specifically



relevant to the achievement of the objectives of USAID Agency Goal 4, with an emphasis on the achievement of the strategic objectives of the G/PHN Center, as described above. The project will also offer technology-related technical assistance that will promote local self-sufficiency in the supply and management of essential health, population and nutrition products. Emphasis will be placed on increasing the public health impact of these products by focusing a significant proportion of the project resources on strategies to ensure their full-scale introduction and appropriate and expanded use in national programs in developing countries. These efforts will be focused on ensuring the introduction and appropriate use of a product or group of quality products employing a similar technological approach and will not be restricted to only those products developed, adapted and/or tested by Health Tech.

In order to facilitate the accessibility, affordability, appropriate use and public health impact of these technologies and to contribute to the achievement of results in the areas of the G/PHN Center's strategic objectives, USAID Health Tech IV staff will work closely with other USAID Cognizant Technical Officers (CTOs) managing G/PHN projects involved in the implementation of health, nutrition and family planning services. USAID Health Tech IV staff will aim to establish essential linkages between USAID's partners who are not USAID grantees or contractors involved in product development and introduction and those involved in implementation activities. In many cases, successful achievement of these strategic objectives will require that the recipient seek the contribution of expertise from outside of the recipient organization and that the recipient work with multiple outside partners (public and private) potentially at multiple stages of the development and/or introduction process. These collaborative efforts will also play an important role in linking the public and the private sector in the provision of appropriate technologies.

### **Illustrative Examples of Past Work Performed Under and Capabilities Provided by Earlier Health Tech Agreements**

USAID and PATH, in partnership with NGOs, CDC, UNICEF, WHO, other global agencies, ministries of health, universities, and private sector companies from developed and developing countries have achieved notable successes under earlier agreements (Health Tech I, II, and III). Examples of the technologies developed, transferred and introduced by these projects are:

- HIV Dipstick, a very low cost, WHO-approved simple HIV test now manufactured in S.E. and S. Asia, and Latin America.
- Vaccine vial monitors (VVMs), the first successful heat exposure monitor for vaccine vials. UNICEF has specified that these vaccine vial monitors (VVMs) will be attached to all vaccine vials supplied through UNICEF starting in 2001. These monitors have allowed WHO/GPV to relax its one-day discard policy for opened oral polio vaccine (OPV), leading to global savings estimated at \$10 million annually.
- SoloShot, the first successful autodisable syringe/needle for vaccine delivery which helps to guarantee that each syringe is used for only one injection.

- UniJect, a prefilled single-use injection system is designed to allow village and mobile health workers to deliver tetanus toxoid to pregnant women. This technology is also showing promise for outreach delivery of hepatitis B vaccine and injectable contraceptives, as well as uterotonics for postpartum hemorrhage control.

Illustrative examples of technical assistance that has been or could be offered by the project to missions and ministries of health include:

- Validation of a locally adapted EPI pressure cooker type sterilizer for sterilization of IUD insertion instruments.
- Seminars on intellectual property trade agreements (i.e., World Trade Organization) and their implications for local conditions, licensing, and working with the private sector.
- Feasibility studies for improving local manufacturing of vaccines, contraceptives, and other essential health, population and nutrition products.
- Regional workshops and individual assistance on local assessment and adaptation of health technologies, and on microenterprise activities related to technologies.
- Building of capacity and capabilities in the areas of quality control, marketing, industrial safety, and procurement.

In addition, the Health Tech project has developed or assisted in the development and field testing of low-cost diagnostics for malaria, schistosomiasis, invasive diarrhea, proteinureas, hepatitis B and several sexually transmitted infections (STIs), and weighing devices for newborns and growth monitoring. These technologies are available through developing world producers and/or from UNICEF. Other technologies include a low-cost needleless injector, a neonatal resuscitator, an acute respiratory infection (ARI ) counter/timer, reusable-birthing gloves, anemia assessment tools and other STI tests.

### **Priority Areas for Technology Development, Technology Introduction and Technical Assistance under Health Tech IV**

Examples of current priority areas for technology development include:

- Family planning-related technologies
- Vaccine safe delivery- and safety-related technologies
- Diagnostics for micronutrient status
- Diagnostics for STIs and other infectious diseases

The technologies listed below, arranged by relevance to G/PHN strategic objectives, are illustrative of the type of technologies that may be further developed by the recipient under the terms of the new Health Tech IV project.

SO 1

- Bundling of injectable contraceptives with AD syringes and a means for safe disposal
- Delivery of injectable contraceptives with a prefilled AD syringe
- Improved female condoms and other barrier methods

SO2

- Introduction of rapid, easy-to-use diagnostic for syphilis
- Innovative means for the rapid and safe delivery of uterotronics
- Neonatal resuscitators

SO3

- Pre-filled, single-use injection systems
- Low-cost, needleless injectors
- Vaccine reconstitution technologies
- Medical waste disposal technologies
- Vitamin A assessment tools
- Improved methods for physical delivery of micronutrients

SO4

- Low cost diagnostics for STIs

SO5

- Low cost diagnostics for malaria and TB
- Reusable gloves

In addition to its efforts in technology development, Health Tech IV will work in close partnership with G/PHN and its other partners to inform and influence global strategies, program directions and approaches related to the introduction and appropriate use of health technologies. The primary focus of these efforts will be on those activities that contribute to the achievement of objectives of the G/PHN Center and those that contribute to the achievement of Agency Goal 4. To this end, Health Tech IV will establish, with assistance from the USAID staff, effective working relations with other USAID cooperating agencies (CAs) and international and developing country partner organizations. These organizations include, but are not limited to, relevant components of WHO, other bilateral donors, private voluntary and non-governmental organizations, foundations, universities and other U.S. and host country government agencies.

## Principal Capabilities

As stated earlier, the Health Tech IV project will support the achievement of G/PHN Center strategic objectives and of Agency Goal 4 through the development and/or introduction of new low-cost health, nutrition, and family planning technologies and the provision of supporting technical assistance. In order to undertake these activities, the Health Tech IV recipient will have the key personnel and its staff required to provide a set “core” and “related” capabilities.

The Health Tech IV recipient will maintain **core** capabilities (provided by “in-house” key personnel and its staff) in the areas of technology development and production, technology introduction, and technical assistance in targeted priority areas that have the greatest impact on the five G/PHN strategic objectives. Targeted priority areas will be identified by USAID working with Health Tech IV staff. The priority interventions of the G/PHN Center currently focus on the following areas: family planning, safe motherhood, child survival, nutrition, HIV/AIDS, STIs and other priority infectious diseases.

The Health Tech IV recipient will maintain access to **related** capabilities (provided by personnel accessible to its key personnel and staff) related to the areas of technology development and production, technology introduction, and technical assistance that will support the population, health and nutrition interventions of USAID Central Bureaus (other than G/PHN) and USAID missions that contribute to the achievement of results under the Agency 4 goal.

### *Core Capabilities*

The skills or expertise listed below are illustrative of **core** capabilities that may be required in areas of **technology development, adaptation, and transfer for local production**:

- Product assessment and selection, adaptation and advancement
- Building of local quality assurance capabilities
- Feasibility studies for local manufacture of key population, health and food and nutrition products
- Development of local laboratory capabilities
- Provision of assistance with development of sustainable systems for maintenance and repair
- Provision of assistance with international intellectual property rights and related trade issues
- Provision of assistance with regulatory approvals and licensing systems
- Acquisition and application of up-to-date knowledge of manufacturing capabilities in the developed and in key developing countries
- Acquisition and application of up-to-date knowledge of manufacturing quality control and quality assurance capabilities in the developing world and in the developed world for products used in the developing world.

The skills or expertise listed below are illustrative of **core** capabilities that may be required in the area of **technology product introduction**:

- Development and implementation of strategies for introduction and appropriate use of technologies in health, nutrition, and family planning intervention activities in the developing world, including intervention activities of the G/PHN Center.
- Analysis of key audiences and stakeholders, including end-users, groups involved in purchasing and distribution, and policy makers
- Assessment of barriers to appropriate use of available technologies at all levels of the health system
- Acquisition and application of knowledge of global disease control- and issue-related strategies, and analysis of issues related to them;
- Acquisition and application of knowledge of programmatic issues related to technology use
- Assessment of local technology needs and/or practices related to the achievement of the five G/PHN Center strategic objectives
- Provision of assistance with the selection and/or the introduction of existing technologies
- Provision of assistance with the introduction of new/adapted technologies
- Acquisition and application of knowledge of logistics and/or procurement systems.

### ***Related Capabilities***

In order to contribute to the achievement of results under Agency Goal 4 that fall outside of the G/PHN Center strategic objectives, the HealthTech IV recipient should have access to the same types of capabilities (as opposed to having those capabilities provided by "in-house" staff and personnel on the project) that are required to meet G/PHN Center goals (listed above under "Core capabilities"). In addition, there may be some additional capabilities that should be accessible through the project to such Agency 4 goals. Illustrative examples include:

- Provision of assistance with the introduction of health and nutrition technologies suitable for uprooted populations and emergency situations
- Development of improved food and quality control for international food assistance.
- Acquisition and application of knowledge of food technology, quality control and quality assurance capabilities.

## **C. GENERAL IMPLEMENTATION PLAN**

The Health Tech IV Program will provide USAID with a mechanism to promote the assessment, development, adaptation, testing, transfer, introduction/application and local manufacturing of state-of-the-art, low-cost, appropriate, and acceptable health, food and nutrition, and family planning technologies and related technical assistance. The Health Tech IV recipient will carry

out activities of the program with substantial USAID involvement. The recipient will provide general management structure and support personnel in the areas of product development and product introduction, management of business agreements, field assessments, technology transfer, and administration. USAID, working with the recipient, will identify impediments to the achievement of USAID health, nutrition, and family planning strategic objectives and, with the recipient, will identify and prioritize potential technology development and introduction needs and technical assistance to address the identified impediments and facilitate strategic technical, programmatic and/or policy linkages with all key partners.

It is assumed that the work encompassed under this agreement will be undertaken largely by one lead organization/consortium. In addition, it is assumed that in order to achieve the steps required for successful technology development or for technology product introduction, the work of the recipient will be supported, as required, by the acquisition of technical, programmatic or policy expertise available through appropriate collaborating institutions and/or sub-contractors. Also to achieve this end, it is expected that the recipient will work strategically and collaboratively with other organizations, CAs and other stakeholders involved in technology development and technology introduction activities. In addition, it is expected that the recipient will explore with the USAID Health Tech IV CTO the opportunity of providing co-funding to the project to facilitate collaborative work or the acquisition of technical expertise (e.g., through a competitive grants program).

### **USAID Substantial Involvement**

The instrument for the Health Tech IV project will be a Cooperative Agreement. Health Tech IV will be administered by the USAID Global Bureau, Office of Health and Nutrition. USAID, through the CTO, shall be substantially involved in administering and monitoring this cooperative agreement. In accordance with ADS 303.5.11a, the specific areas of USAID CTO involvement in the cooperative agreements are as follows:

- 1) Approval of the Recipients' Product Development and Product Introduction Plans (as described in Section C, "Technical Activities");
- 2) Approval of specified key personnel;
- 3) Agency and Recipient collaboration joint participation: (a) concur on the selection of sub-award recipients and/or the substantive provisions of the sub-awards; (b) approval of the Recipient's monitoring and evaluation plans; and (c) agency monitoring to permit specified kinds of direction or redirection because of interrelationships with other projects; and
- 4) Participation in site visits, any expert meetings, and evaluations to review specific subprojects as appropriate.

Additionally, USAID missions will approve country work plans for activities undertaken with field support funding.

The Agreement Officer is the ONLY USAID official representative of the Government authorized to change any terms and conditions of the Cooperative Agreement.

In accordance with the specific areas of involvement authorized by ADS 303.5.11a, USAID CTO involvement in the Health Tech IV cooperative agreement will be as follows:

- 1) Collaborative Development and Approval of the Annual Product Development and Product Introduction Plans for Health, Nutrition and Family Planning Technology Development and Introduction Activities, and All Modifications.*

As stated above, USAID will work with the recipient to identify impediments to the achievement of USAID Agency Goal 4 and the achievement of USAID G/PHN Center strategic objectives. The USAID CTO will work with each of the G/PHN Center strategic objective teams to identify technology-related constraints that limit the teams' ability to achieve their objectives in a timely, efficient, and/or cost-effective fashion.

During the first year in which the cooperative agreement is awarded, USAID will work with the recipient to identify potential technology development and introduction areas of need and associated technical assistance as potential areas to target in order to address the identified impediments to health, nutrition and family planning service interventions in the developing world.

After a set of potential areas have been identified, the recipient will be asked to carry out and provide to USAID a feasibility analysis for each area identified in order to assess whether feasible technology development or technology introduction solutions exist. The feasibility analysis should provide sufficient critical information to USAID staff to aid them in assessing whether or not the issue merits attention and should be given priority.

As part of this process, activities performed by the recipient will include, but be not limited to: describe the burden of disease to be addressed; describe the impediment to be addressed; assess existing technologies and current approaches; describe how the proposed technology or technical assistance will replace, complement or increase the impact of existing approaches; review other programs carrying out similar work; review and/or conduct need, cost-analysis and potential impact studies; review and/or conduct market surveys; and identify critical technical, programmatic and policy stakeholders (including providers and end-users), including their needs and roles. The recipient will provide this information to USAID.

USAID will use this information, in conjunction with programmatic considerations, to recommend specific products for development or introduction and associated selected technical assistance to be provided under the terms of this agreement. USAID will work with the recipient to facilitate the required technical, programmatic and/or policy linkages with all key partners.

Initially, each USAID G/PHN Center Strategic Objective team will identify and recommend two or three priority target areas for Health Tech IV project investment. USAID and the recipient will attempt to strike a balance between short-and long-term investments, regional and global impact, and human resource requirements. As priority target areas are successfully addressed,

USAID and the recipient will work with the SO teams to identify new priority targets for investment. The recipient will be asked to conduct feasibility analyses in order to provide information to USAID staff to aid in assessing whether or not the new target area merits further attention and should be given priority.

The recipient will prepare and maintain, depending on its status, a detailed Product Development Plan (PDP) or Product Introduction Plan (PIP) for each product to be provided under the terms of this agreement. These plans will be submitted to the USAID CTO for approval prior to committing resources. The CTO will approve significant changes to these plans. The PDPs and PIPs will serve as the principal management tool of the Health Tech IV CTO.

*2) Collaborative Development and Approval of All Work Plans for Technical Assistance Activities.*

The Health Tech IV CTO will give final approval to the recipient for carrying out activities to provide technical assistance in response to USAID mission and USAID bureau requests in support of USAID mission-assisted health product development and introduction/application at the local level.

*3) Approval of the Selection of Individuals to Serve as Key Personnel and of Changes in Key Personnel*

To achieve the objectives and results established for the cooperative agreement, the recipient shall provide key personnel and a core staff of highly qualified and experienced experts with demonstrated skill and effectiveness in contributing to the areas of technology development and technology introduction and associated technical assistance and able to provide the capabilities required to successfully carry out these activities.

The USAID Health Tech CTO will approve all key personnel. Throughout the life of the cooperative agreement, any change in the key personnel will require the prior written consent of the CTO and the Agreement Officer.

This RFA identifies only one key personnel position, that of Project Leader. The Project Leader shall be responsible for oversight, administration, supervision and management of all aspects of cooperative agreement performance. S/he shall coordinate and collaborate with other USAID-funded cooperating agencies and other donors (e.g., bi- and multi-national agencies and foundations) and their contractors, as well as with other key partners, such as industry and academia. A successful candidate should have extensive experience in health, nutrition and family planning technology development and introduction, as well as substantial experience and demonstrated success in executive management of international health projects; effectiveness as a leader, decision maker, team builder, problem solver, and as a visionary collaborator; working knowledge of USAID activity management; and excellent speaking, representational, networking, advocacy and written communication skills.



In addition to the proposed key personnel, the recipient shall provide a staff of technical staff/advisors and program support staff that will work with and support the key personnel. As with key personnel, technical and program staff should be expected to possess expertise in the critical capability and skill areas identified in this program description.

As stated above, it is expected that in order to achieve the steps required for successful technology development and technology product introduction and associated technical assistance as well as to provide some areas of capability not provided by the recipient's staff, the work of the recipient will be supported, as required, by the acquisition of or collaboration with technical, programmatic or policy expertise available through appropriate collaborating institutions and/or sub-contractors.

#### *4) Collaborative Development and Approval of Monitoring and Evaluation Plans.*

The USAID Health Tech CTO will monitor performance and progress related to the implementation of activities described in annual work plans on a bi-annual basis. The USAID Health Tech IV CTO and the recipient will use these opportunities to jointly review constraints or opportunities that are affecting, or could in the future affect, the performance and/or progress of current and planned activities described in Product Development Plans (PDPs) and Product Introduction Plans (PIPs), and to recommend adjustments to be made in the PDPs and PIPs, and subsequently to the annual work plan.

## **Technical Reporting**

The recipient will prepare and submit the following plans and reports to the G/PHN CTO. Final acceptance of reports shall be subject to review and approval by the CTO.

### **Annual Work plans**

Annual work plans will consist of information, excised or summarized from PDPs and PIPs, for each health, nutrition or family planning technology product project in the Health Tech IV portfolio. Information for each project should include: budget, activities completed in the previous year, activities proposed for the upcoming year and goals and expected outcomes for the upcoming year.

The first annual work plan should be submitted no later than 120 days after the award of the cooperative agreement.

### **Annual Reports**

Bi-annual report of progress for all components of the PDPs and PIPs should be timed to provide USAID bureaus and missions with input required for annual R4 and results review reporting

requirements. The reports should also provide recommendations regarding future programs, technical priorities, and approaches; identify important issues or problems affecting program implementation and progress; and suggest appropriate adjustments as indicated.

## **Final Report**

The recipient will submit a final report no later than 90 days after the completion date of the cooperative agreement. The report should include a description of the final status of activities and the outcomes and goals achieved for each health, nutrition and family planning product development and introduction project carried out during the course of the agreement. The report should include recommendations concerning follow-up activities to the work completed under this cooperative agreement; conclusions regarding future program and policy directions, challenges and approaches; recommendations regarding important issues, problems, key players and effective approaches to achieving further progress in the area of health, nutrition and family planning technology development and introduction through the use of U.S. development assistance. The report should also include a financial summary describing how USAID funds were used and the effort that went into implementation of the cooperative agreement activities.

## **C. TECHNICAL ACTIVITIES**

### **Feasibility Analysis**

Feasibility analyses (as described earlier in more detail under "USAID Substantial Involvement, (1)") will be principal tool for assessing whether identified health, nutrition and family planning technology development and introduction areas of need merit further attention and should be given priority. If the decision is made that the technology product development or technology introduction activity in response to this need should be pursued, a Product Development Plan or a Product Introduction Plan will be developed by the recipient.

### **Product Development**

Product Development Plans (PDPs) will be the principal tool for outlining the technical strategy for the development and introduction of “new”/improved products. Plans will cover the development process beginning with the current status of the product to full deployment in the developing world.

Each plan will include, but be not limited to, the following:

- a) An analysis of the impediment(s) to the delivery of health, food and nutrition, and family planning services to be addressed by the technology or the technical assistance.
- b) A description of current approaches, technologies or products to address the identified impediment, and a discussion of the strengths or weaknesses of the approaches;

- c) A summary of past activities and achievements associated with the product;
- d) A discussion of the current global disease control strategies or strategies associated with issues relevant to the product (including key organizations, agencies, and others involved); how the product could impact on those strategies; and how the recipient will coordinate with and contribute to those strategies;
- e) A description of key technical, programmatic and/or policy stakeholders;
- f) A discussion of the major issues associated with the introduction of current methods, technologies or products and those that might be associated with the introduction of the proposed product if successfully developed;
- g) The proposed specifications and anticipated scenarios of use of the new/improved technology;
- h) A cost-analysis of the product and a discussion of the potential financing and procurement mechanisms that could be used by the end-user;
- i) A list of the Health Tech team personnel and other collaborating partners involved in development efforts, their area of expertise and specific roles;
- j) A timeline for development;
- k) An estimated cost for the financial investment in each stage of development.

## **Product Introduction**

Product Introduction Plans (PIPs) will be the principal tool for outlining the technical strategy for integrating new technologies into health, nutrition and family planning activities to ensure that their maximum public health impact is achieved in a timely and efficient manner. The technologies that will be considered for these introduction activities will have completed a proof of concept stage or have been successfully commercialized by at least one manufacturer.

Plans will cover the development process beginning with the current status of the product to the point at which the Health Tech IV project recipient will withdraw support. Emphasis will be placed on close collaboration of the Health Tech IV Project with other partners for the implementation of product introduction activities. Activities should be consistent with and contribute to global disease control (or global health-related) efforts and initiatives.

The objectives of the Health Tech IV Program are to develop and introduce technologies to address impediments to the delivery of health, nutrition and family planning services. Consequently, emphasis will be placed on a comprehensive, cohesive product introduction plan that outlines activities, capabilities and collaborating partners required to take the technology from its current state to an outcome in which the product has demonstrated a significant public health impact (e.g., its introduction and appropriate use in intervention/prevention programs).

Plans should contain a clear strategy including desired outcomes for proposed activities and how achievement of those short-term outcomes will contribute to the achievement of the overall objective and more long-term goal of achieving a significant public health impact through widespread appropriate use of the product in intervention/prevention programs. The plans should clearly outline how the recipient will receive input from and/or work with key public and

private-sector stakeholders (e.g., product developers, producers, distributors, global and national policy and decision makers, health service providers and users) in order to achieve the identified short- and long-term objectives.

Each plan will include, but be not limited to, the following:

- a) Background. This should include an analysis of all aspects of the performance of existing products and technologies based on a review of the literature, including: rationale for product development; performance and ease-of-use in the field; status of current efforts of the Health Tech IV recipient and its partners, as well as of others involved in related product development and introduction activities; current product introduction approaches (successful or not); challenges and issues associated with current introduction approaches as well as those proposed by the recipient (if different); current global disease control or issue-related strategies and the approach that will be taken by the recipient to coordinate with and contribute to these strategies; key stakeholders, including policy and decision makers, implementers, providers and users;
- b) A description of scenarios of use of the new/improved product;
- c) A discussion of how the introduction of the new/improved product will impact on current methods and relevant health systems issues, as well as how the new/improved product will impact on the targeting or execution of interventions and on outcomes;
- d) A scope of work regarding current and future activities that will be required to take the product from its current state to the point at which the Health Tech IV recipient will withdraw support;
- e) The anticipated project financial and personnel investments required;
- f) A list of the Health Tech project team personnel and collaborators, including their areas of expertise and specific roles.
- g) Timeline.

The technologies listed below are illustrative of the type of technologies that have reached the stage where they warrant coordinated and comprehensive introduction efforts under the terms of the new Health Tech IV project.

- Diagnostics for HIV, malaria and syphilis
- Vaccine Vial Monitors

## **Technical Assistance**

The Health Tech IV recipient may also provide technical assistance to USAID missions and USAID bureaus in support of the proposed activity. These activities will be limited to responding to USAID mission or USAID bureau requests and will not be supported by core G/PHN funds. This technical assistance is designed to support mission-assisted health product development and introduction/application at the local level. Technical assistance will be available in the following illustrative areas:

- Assessment of existing local technology needs and/or practices
- Product assessment and selection, adaptation and advancement
- Assistance with selection of existing technologies
- Training in procurement and distribution systems
- Building of local quality assurance capabilities
- Feasibility studies for local manufacture of key population, health, and food and nutrition products
- Development of laboratory capabilities
- Assistance with maintenance and repair systems
- Assistance with intellectual property and regulatory systems
- Assistance with introduction of new/adapted technologies and products
- Technology transfer for local production of all relevant technologies
- Assistance with new technologies for improved food and commodities
- Health and nutrition technologies for refugees

As stated above, USAID will play a role of substantial involvement in the area of technical assistance. All technical assistance activities and their respective work plans will be reviewed and approved by the Health Tech CTO before implementation.

### **Applicant-Initiated Activities**

A limited amount of resources will be set aside each year to support applicant-initiated activities. The purpose of these activities will be to investigate the potential of new, innovative technologies consistent with USAID's Agency 4 and G/PHN Center objectives and to develop them to the point where a feasibility analysis can be undertaken and subsequently considered by the USAID SO teams as priority target areas. The use of these funds to initiate activities will not require the approval of the USAID Health Tech CTO and will be used at the discretion of the Health Tech IV staff; however, oversight of these funds and activities will be similar to that of Health Tech IV's other activities in that once activities have been initiated, PDPs or PIPs will be developed by the applicant and included in the annual work plan.

# Section D

## U.S. Agency for International Development

### CERTIFICATIONS, ASSURANCES, AND OTHER STATEMENTS OF RECIPIENT<sup>1 2</sup>

#### PART I - CERTIFICATIONS AND ASSURANCES

##### **1. ASSURANCE OF COMPLIANCE WITH LAWS AND REGULATIONS GOVERNING NON-DISCRIMINATION IN FEDERALLY ASSISTED PROGRAMS**

(a) The recipient hereby assures that no person in the United States shall, on the bases set forth below, be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under, any program or activity receiving financial assistance from USAID, and that with respect to the grant for which application is being made, it will comply with the requirements of:

(1) Title VI of the Civil Rights Act of 1964 (Pub. L. 88-352, 42 U.S.C. 2000-d), which prohibits discrimination on the basis of race, color or national origin, in programs and activities receiving Federal financial assistance;

(2) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), which prohibits discrimination on the basis of handicap in programs and activities receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as amended (Pub. L. 95-478), which prohibits discrimination based on age in the delivery of services and benefits supported with Federal funds;

(4) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681, et seq.), which prohibits discrimination on the basis of sex in education programs and activities receiving Federal financial assistance (whether or not the programs or activities are offered or sponsored by an educational institution); and

(5) USAID regulations implementing the above nondiscrimination laws, set forth in Chapter II of Title 22 of the Code of Federal Regulations.

(b) If the recipient is an institution of higher education, the Assurances given herein extend to admission practices and to all other practices relating to the treatment of students or clients of the institution, or relating to the opportunity to participate in the provision of services or other benefits to such individuals, and shall be applicable to the entire institution unless the recipient establishes to the satisfaction of the USAID Administrator that the institution's practices in designated parts or programs of the institution will in no way affect its practices in the program of the institution for which financial assistance is sought, or the beneficiaries of, or participants in, such programs.

(c) This assurance is given in consideration of and for the purpose of obtaining any and all Federal grants, loans, contracts, property, discounts, or other Federal financial assistance extended after the date hereof to the recipient by the Agency, including installment payments after such date on account of applications for Federal financial assistance which were approved before such date. The recipient recognizes and agrees that such Federal financial assistance will be extended in reliance on the representations and agreements made in this Assurance, and that the United States shall have the right to seek judicial enforcement of this Assurance. This Assurance is binding on the recipient, its successors, transferees, and assignees, and the person or persons whose signatures appear below are authorized to sign this Assurance on behalf of the recipient.

##### **2. CERTIFICATION REGARDING DRUG-FREE WORKPLACE REQUIREMENTS**

###### **(a) Instructions for Certification**

(1) By signing and/or submitting this application or grant, the recipient is providing the certification set out below.

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<sup>1</sup>FORMATS\GRNTECERT: Rev. 06/16/97 (ADS 303.6, E303.5.6a)

<sup>2</sup>When these Certifications, Assurances, and Other Statements of Recipient are used for cooperative agreements, the term "Grant" means "Cooperative Agreement".

(2) The certification set out below is a material representation of fact upon which reliance was placed when the agency determined to award the grant. If it is later determined that the recipient knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

(3) For recipients other than individuals, Alternate I applies.

(4) For recipients who are individuals, Alternate II applies.

(b) Certification Regarding Drug-Free Workplace Requirements

Alternate I

(1) The recipient certifies that it will provide a drug-free workplace by:

(A) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the applicant's/grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(B) Establishing a drug-free awareness program to inform employees about--

1. The dangers of drug abuse in the workplace;
2. The recipient's policy of maintaining a drug-free workplace;
3. Any available drug counseling, rehabilitation, and employee assistance programs; and
4. The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(C) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (b)(1)(A);

(D) Notifying the employee in the statement required by paragraph (b)(1)(A) that, as a condition of employment under the grant, the employee will--

1. Abide by the terms of the statement; and
2. Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;

(E) Notifying the agency within ten days after receiving notice under subparagraph (b)(1)(D)1. from an employee or otherwise receiving actual notice of such conviction;

(F) Taking one of the following actions, within 30 days of receiving notice under subparagraph (b)(1)(D)2., with respect to any employee who is so convicted--

1. Taking appropriate personnel action against such an employee, up to and including termination; or
2. Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(G) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (b)(1)(A), (b)(1)(B), (b)(1)(C), (b)(1)(D), (b)(1)(E) and (b)(1)(F).

(2) The recipient shall insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

Alternate II

The recipient certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance in conducting any activity with the grant.

**3. CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS -- PRIMARY COVERED TRANSACTIONS<sup>3</sup>**

**(a) Instructions for Certification**

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.
2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.
3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.
4. The prospective primary participant shall provide immediate written notice to the department or agency to whom this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meaning set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549.<sup>4</sup> You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.
6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.
7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion--Lower Tier Covered Transaction,"<sup>5</sup> provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the methods and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.
9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealing.
10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

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<sup>3</sup>The recipient must obtain from each identified subgrantee and (sub)contractor, and submit with its application/proposal, the Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion -- Lower Tier Transactions, set forth in Attachment A hereto. The recipient should reproduce additional copies as necessary.

<sup>4</sup>See ADS Chapter E303.5.6a, 22 CFR 208, Annex1, App A.

<sup>5</sup>For USAID, this clause is entitled "Debarment, Suspension, Ineligibility, and Voluntary Exclusion (March 1989)" and is set forth in the grant standard provision entitled "Debarment, Suspension, and Related Matters" if the recipient is a U.S. nongovernmental organization, or in the grant standard provision entitled "Debarment, Suspension, and Other Responsibility Matters" if the recipient is a non-U.S. nongovernmental organization.



(b) Certification Regarding Debarment, Suspension, and Other Responsibility Matters--Primary Covered Transactions

(1) The prospective primary participant certifies to the best of its knowledge and belief, the it and its principals:

(A) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(B) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(C) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(B) of this certification;

(D) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

**4. CERTIFICATION REGARDING LOBBYING**

The undersigned certifies, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form LLL, "Disclosure of Lobbying Activities,"<sup>6</sup> in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, United States Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

**Statement for Loan Guarantees and Loan Insurance**

The undersigned states, to the best of his or her knowledge and belief, that: If any funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this commitment providing for the United States to insure or guarantee a loan, the undersigned shall complete and submit Standard Form LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions. Submission of this statement is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required statement shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

**5. Prohibition on Assistance to Drug Traffickers for Covered Countries and Individuala (ADS 206)**

**USAID reserves the right to terminate this [Agreement/Contract], to demand a refund or take other appropriate measures if the [Grantee/Contractor] is found to have been convicted of a narcotics offense or to have been engaged in drug trafficking as defined in 22 CFR Part 140. The undersigned shall review USAID ADS 206 to determine if any certification are required for Key Individuals or Covered Participants.**

**If there are COVERED PARTICIPANTS: USAID reserves the right to terminate assistance to, or take or take other appropriate measures with respect to, any participant approved by USAID who is found to have been convicted of a narcotics offense or**

to have been engaged in drug trafficking as defined in 22 CFR Part 140.

**6. CERTIFICATION OF RECIPIENT**

The recipient certifies that it has reviewed and is familiar with the proposed grant format and the regulations applicable thereto, and that it agrees to comply with all such regulations, except as noted below (use a continuation page as necessary):

Solicitation No.

Application/Proposal No.

Date of Application/Proposal

Name of Recipient

Typed Name and Title

Signature \_\_\_\_\_ Date

## **PART II**

### **OTHER STATEMENTS OF RECIPIENT**

#### **1. AUTHORIZED INDIVIDUALS**

The recipient represents that the following persons are authorized to negotiate on its behalf with the Government and to bind the recipient in connection with this application or grant:

Name

Title

Telephone No.

Facsimile No.

#### **2. TAXPAYER IDENTIFICATION NUMBER (TIN)**

If the recipient is a U.S. organization, or a foreign organization which has income effectively connected with the conduct of activities in the U.S. or has an office or a place of business or a fiscal paying agent in the U.S., please indicate the recipient's TIN:

TIN:

#### **3. CONTRACTOR IDENTIFICATION NUMBER--DATA UNIVERSAL NUMBERING SYSTEM (DUNS) NUMBER**

(a) In the space provided at the end of this provision, the recipient should supply the Data Universal Numbering System (DUNS) number applicable to that name and address. Recipients should take care to report the the number that identifies the recipient's name and address exactly as stated in the proposal.

(b) The DUNS is a 9-digit number assigned by Dun and Bradstreet Information Services. If the recipient does not have a DUNS number, the recipient should call Dun and Bradstreet directly at 1-800-333-0505. A DUNS number will be provided immediately by telephone at no charge to the recipient. The recipient should be prepared to provide the following information:

- (1) Recipient's name.
- (2) Recipient's address.
- (3) Recipient's telephone number.
- (4) Line of business.
- (5) Chief executive officer/key manager.
- (6) Date the organization was started.
- (7) Number of people employed by the recipient.
- (8) Company affiliation.

(c) Recipients located outside the United States may obtain the location and phone number of the local Dun and Bradstreet Information Services office from the Internet Home Page at <http://www.dbisna.com/dbis/customer/custlist.htm>. If an offeror is unable to locate a local service center, it may send an e-mail to Dun and Bradstreet at [globalinfo@dbisma.com](mailto:globalinfo@dbisma.com).

The DUNS system is distinct from the Federal Taxpayer Identification Number (TIN) system.

DUNS:

#### **4. LETTER OF CREDIT (LOC) NUMBER**

If the recipient has an existing Letter of Credit (LOC) with USAID, please indicate the LOC number:

LOC: 72-00-

#### **5. PROCUREMENT INFORMATION**

(a) Applicability. This applies to the procurement of goods and services planned by the recipient (i.e., contracts, purchase orders, etc.) from a supplier of goods or services for the direct use or benefit of the recipient in conducting the program supported by the grant, and not to assistance provided by the recipient (i.e., a subgrant or subagreement) to a subgrantee or subrecipient in support of the subgrantee's or subrecipient's program. Provision by the recipient of the requested information does not, in and of itself, constitute USAID approval.

(b) Amount of Procurement. Please indicate the total estimated dollar amount of goods and services which the recipient plans to purchase under the grant:

       \$

(c) Nonexpendable Property. If the recipient plans to purchase nonexpendable equipment which would require the approval of the Agreement Officer, please indicate below (using a continuation page, as necessary) the types, quantities of each, and estimated unit costs. Nonexpendable equipment for which the Agreement Officer's approval to purchase is required is any article of nonexpendable tangible personal property charged directly to the grant, having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit.

<u>Type/Description (Generic)</u>	<u>Quantity</u>	<u>Estimated Unit Cost</u>
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(d) Source, Origin, and Componentry of Goods. If the recipient plans to purchase any goods/commodities which are not of U.S. source and/or U.S. origin, and/or does not contain at least 50% componentry which are not at least 50% U.S. source and origin, please indicate below (using a continuation page, as necessary) the types and quantities of each, estimated unit costs of each, and probable source and/or origin, to include the probable source and/or origin of the components if less than 50% U.S. components will be contained in the commodity. "Source" means the country from which a commodity is shipped to the cooperating country or the cooperating country itself if the commodity is located therein at the time of purchase. However, where a commodity is shipped from a free port or bonded warehouse in the form in which received therein, "source" means the country from which the commodity was shipped to the free port or bonded warehouse. Any commodity whose source is a non-Free World country is ineligible for USAID financing. The "origin" of a commodity is the country or area in which a commodity is mined, grown, or produced. A commodity is produced when, through manufacturing, processing, or substantial and major assembling of components, a commercially recognized new commodity results, which is substantially different in basic characteristics or in purpose or utility from its components. Merely packaging various items together for a particular procurement or relabeling items does not constitute production of a commodity. Any commodity whose origin is a non-Free World country is ineligible for USAID financing. "Components" are the goods which go directly into the production of a produced commodity. Any component from a non-Free World country makes the commodity ineligible for USAID financing.

<u>Type/Description</u>	<u>Quantity</u>	<u>Unit Cost</u>	<u>Goods</u>	<u>Estimated Components</u>	<u>Probable Source Goods</u>	<u>Components</u>	<u>Probable Origin</u>	<u>(Generic)</u>
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(e) Restricted Goods. If the recipient plans to purchase any restricted goods, please indicate below (using a continuation page, as necessary) the types and quantities of each, estimated unit costs of each, intended use, and probable source and/or origin. Restricted goods are Agricultural Commodities, Motor Vehicles, Pharmaceuticals, Pesticides, Rubber Compounding Chemicals and Plasticizers, Used Equipment, U.S. Government-Owned Excess Property, and Fertilizer.

<u>Type/Description</u>	<u>Quantity</u>	<u>Unit Cost</u>	<u>Intended Use</u>	<u>Estimated Source</u>	<u>Origin</u>	<u>Probable</u>	<u>Probable</u>	<u>(Generic)</u>
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(f) Supplier Nationality. If the recipient plans to purchase any goods or services from suppliers of goods and services whose nationality is not in the U.S., please indicate below (using a continuation page, as necessary) the types and quantities of each good or service, estimated costs of each, probable nationality of each non-U.S. supplier of each good or service, and the rationale for purchasing from a non-U.S. supplier. Any supplier whose nationality is a non-Free World country is ineligible for USAID financing.

<u>Type/Description (Generic)</u>	<u>Quantity</u>	<u>Unit Cost</u>	<u>Estimated</u>	<u>Probable Supplier Nationality (Non-U.S. Only)</u>	<u>Rationale for non-U.S.</u>
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(g) Proposed Disposition. If the recipient plans to purchase any nonexpendable equipment with a unit acquisition cost of \$5,000 or more, please indicate below (using a continuation page, as necessary) the proposed disposition of each such item. Generally, the recipient may either retain the property for other uses and make compensation to USAID (computed by applying the percentage of federal participation in the cost of the original program to the current fair market value of the property), or sell the property and reimburse USAID an amount computed by applying to the sales proceeds the percentage of federal participation in the cost of the original program (except that the recipient may deduct from the federal share \$500 or 10% of the proceeds, whichever is greater, for selling and handling expenses), or donate the property to a host country institution, or otherwise dispose of the property as instructed by USAID.

<u>Type/Description (Generic)</u>	<u>Quantity</u>	<u>Estimated Unit Cost</u>	<u>Proposed Disposition</u>
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**6. PAST PERFORMANCE REFERENCES**

On a continuation page, please provide a list of the ten most current U.S. Government and/or privately-funded contracts, grants, cooperative agreements, etc., and the name, address, and telephone number of the Contract/Agreement Officer or other contact person.

**7. TYPE OF ORGANIZATION**

The recipient, by checking the applicable box, represents that -

(a) If the recipient is a U.S. entity, it operates as ☐ a corporation incorporated under the laws of the State of \_\_\_\_\_, ☐ an individual, ☐ a partnership, ☐ a nongovernmental nonprofit organization, ☐ a state or local governmental organization, ☐ a private college or university, ☐ a public college or university, ☐ an international organization, or ☐ a joint venture; or

(b) If the recipient is a non-U.S. entity, it operates as ☐ a corporation organized under the laws of \_\_\_\_\_ (country), ☐ an individual, ☐ a partnership, ☐ a nongovernmental nonprofit organization, ☐ a nongovernmental educational institution, ☐ a governmental organization, ☐ an international organization, or ☐ a joint venture.

**8. ESTIMATED COSTS OF COMMUNICATIONS PRODUCTS**

The following are the estimate(s) of the cost of each separate communications product (i.e., any printed material [other than non-color photocopy material], photographic services, or video production services) which is anticipated under the grant. Each estimate must include all the costs associated with preparation and execution of the product. Use a continuation page as necessary.

**Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion**  
**Lower Tier Covered Transactions**

(a) Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.
2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.
3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.
4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, has the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. <sup>1/</sup> You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.
5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.
6. The prospective lower tier participant further agrees by submitting this proposal that it will include this clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion--Lower Tier covered Transaction," <sup>2/</sup> without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.
7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Non procurement List.
8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.
9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

<sup>1/</sup> See ADS Chapter 303, 22 CFR 208.

<sup>2/</sup> For USAID, this clause is entitled "Debarment, Suspension, Ineligibility, and Voluntary Exclusion (March 1989)" and is set forth in the USAID grant standard provision for U.S. nongovernmental organizations entitled "Debarment, Suspension, and Related Matters" (see ADS Chapter 303), or in the USAID grant standard provision for non-U.S. nongovernmental organizations entitled "Debarment, Suspension, and Other Responsibility Matters" (see ADS Chapter 303).

(b) Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion--Lower Tier Covered Transactions

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Solicitation No.  
Application/Proposal No.  
Date of Application/Proposal  
Name of Applicant/Subgrantee  
Typed Name and Title

Signature\_\_\_\_\_ Date

## KEY INDIVIDUAL CERTIFICATION NARCOTICS OFFENSES AND DRUG TRAFFICKING

I hereby certify that within the last ten years:

1. I have not been convicted of a violation of, or a conspiracy to violate, any law or regulation of the United States or any other country concerning narcotic or psychotropic drugs or other controlled substances.
2. I am not and have not been an illicit trafficker in any such drug or controlled substance.
3. I am not and have not been a knowing assistor, abettor, conspirator, or colluder with others in the illicit trafficking in any such drug or substance.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Title/Position: \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
Date of Birth: \_\_\_\_\_

### NOTICE:

1. You are required to sign this Certification under the provisions of 22 CFR Part 140, Prohibition on Assistance to Drug Traffickers. These regulations were issued by the Department of State and require that certain key individuals of organizations must sign this Certification.
2. If you make a false Certification you are subject to U.S. criminal prosecution under 18 U.S.C. 1001.



## PARTICIPANT CERTIFICATION NARCOTICS OFFENSES AND DRUG TRAFFICKING

1. I hereby certify that within the last ten years:

a. I have not been convicted of a violation of, or a conspiracy to violate, any law or regulation of the United States or any other country concerning narcotic or psychotropic drugs or other controlled substances.

b. I am not and have not been an illicit trafficker in any such drug or controlled substance.

c. I am not or have not been a knowing assistor, abettor, conspirator, or colluder with others in the illicit trafficking in any such drug or substance.

2. I understand that USAID may terminate my training if it is determined that I engaged in the above conduct during the last ten years or during my USAID training.

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_  
Date of Birth: \_\_\_\_\_

### NOTICE:

1. You are required to sign this Certification under the provisions of 22 CFR Part 140, Prohibition on Assistance to Drug Traffickers. These regulations were issued by the Department of State and require that certain participants must sign this Certification.

2. If you make a false Certification you are subject to U.S. criminal prosecution under 18 U.S.C. 1001.

## SECTION E

### ANNEXES

For information about the strategic objectives and activities of the Global Bureau, Center for Population, Health and Nutrition, refer to the following web-sites:

[http://www.usaid.gov/pop\\_health](http://www.usaid.gov/pop_health)

[http://www.usaid.gov/pop\\_health/resource/phnsp.htm](http://www.usaid.gov/pop_health/resource/phnsp.htm)

[http://www.usaid.gov/pop\\_health/pdf/stratpln](http://www.usaid.gov/pop_health/pdf/stratpln)

[http://www.usaid.gov/pop\\_health/pdf/csguidance](http://www.usaid.gov/pop_health/pdf/csguidance)

For information about activities undertaken by the recipient of earlier Health Tech agreements, refer to: <http://www.path.org/programs/healthtech.htm>

For Standard Forms 424 and 424A, and instructions, refer to ANNEX F at:

<http://www.usaid.gov/pubs/ads/200/pvoguide.pdf>